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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/675,525	09/29/2000	Ronald W. Barrett	019282-000210US	1576

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EXAMINER

FRIEND, TOMAS H F

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 01/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/675,525

Applicant(s)

BARRETT ET AL.

Examiner

Tomas Friend

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 April 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-126 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-126 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____.                                   |

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## **Detailed Action**

### **Change of Art Unit Designation**

**Please note:** The Art Unit location of this application in the PTO has changed from Art Unit 1627 to Art Unit 1639. To aid in matching papers to this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

### **Status of the Application**

Receipt is acknowledged of a response to a notice to comply with sequence rules on 12 April 2002 (Paper No. 12).

### **Status of the Claims**

Claims 1-126 are pending in the present application and are subject to restriction and election of species requirements.

### **Restriction**

Please note that claims 125 and 126 cannot be assigned to an invention because claim 125 is incomplete (i.e. ends with the word "*and*" and does not end with a period).

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-44, drawn to a replicable genetic package displaying a compound other than an expressed polypeptide comprising a heterologous nucleic acid tag encoding a characteristic of the compound, classified in class 435, subclass 252.3.

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- II. Claims 45-54, drawn to a replicable genetic package displaying a compound other than an expressed polypeptide wherein the replicable genetic package and the compound are attached via a linker, classified in class 435, subclass 243.
- III. Claims 55-50, drawn to a replicable genetic package displaying a compound comprising a heterologous nucleic acid tag encoding a characteristic of the compound by a code other than the standard genetic code, classified in class 435, subclass 235.1.
- IV. Claims 61-106, drawn to a method of screening a library of compounds comprising providing a plurality of replicable genetic packages displaying different compounds wherein the compounds are other than expressed polypeptides, classified in class 435, digest 8.
- V. Claims 107-124, drawn to a method of screening a library of compounds comprising providing a plurality of different replicable genetic packages, each displaying a compound are other than an expressed polypeptide, different replicable genetic packages displaying different compounds and harboring different heterologous nucleic acid tags, classified in class 435, digest 3.

The inventions are distinct, each from the other because:

Inventions I-III are different and patentably distinct compositions because they have different chemical structures with different chemical, physical, and/or biological properties. For example, the replicable genetic package of Invention III comprises a compound that can be a polypeptide encoded by nucleic acid within the package, unlike Inventions I and II. The replicable genetic package of Invention II comprises a linker between the package and a compound, unlike Inventions I and III.

Inventions IV and V are different and patentably distinct methods because they involve different method steps, starting materials, reagents, and/or reaction conditions and/or produce different products or results. For example, Invention IV does not require heterologous nucleic acid tags or a decoding step, while Invention V does.

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Inventions I-III and Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the processes of Inventions IV and V can be practiced with various combinations of the compositions of Inventions I-III or with pluralities of compositions of Inventions I or II or III.

Because these inventions are distinct for the reasons given above and

- a. have acquired a separate status in the art as shown by their different classification ;
- b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
- c. have divergent subject matter, restriction for examination purposes as indicated is proper.

2. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under CFR 1.17(h).

### **Election of Species**

3. This application contains claims directed to patentably distinct species of the claimed inventions. If applicants elect Invention I, applicants are required to elect a species for each of the following A-D.

- A. Ultimate species of displaying (i.e. specific linker(s), binding partners, etc.),
- B. Ultimate species of compound(s) (i.e. specific chemical structure),
- C. Ultimate species of nucleic acid tag (i.e. specific structure/sequence),
- D. Ultimate species of replicable genetic package (e.g. specific viral, phage, or bacterial strain).

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If applicants elect Invention II, applicants are required to elect a species for each of the following A-C.

- A. Ultimate species of linker (i.e. specific structure),
- B. Ultimate species of compound(s) (i.e. specific chemical structure), AND
- C. Ultimate species of replicable genetic package (e.g. specific viral, phage, or bacterial strain).

If applicants elect Invention III, applicants are required to elect a species for each of the following A-E.

- A. Ultimate species of displaying (i.e. specific linker(s), binding partners, etc.),
- B. Ultimate species of compound(s) (i.e. specific chemical structure),
- C. Ultimate species of nucleic acid tag (i.e. specific structure/sequence),
- D. Ultimate species of desired property (e.g. specific enzymatic activity, transport through a type of cell, binding to a particular receptor or ligand), AND
- E. Species of code other than the standard genetic code.

If applicants elect Invention IV, applicants are required to elect a species for each of the following A-D.

- A. Ultimate species of displaying (i.e. specific linker(s), binding partners, etc.),
- B. Species of compounds (e.g. peptides, nucleic acids, specified group of structurally related small organic molecules or inorganic molecules),
- C. Ultimate species of replicable genetic package (e.g. specific viral, phage, or bacterial strain), AND,
- D. Ultimate species of assay including desired property and all method steps including, e.g., the method of contacting and what is being contacted.

If applicants elect Invention V, applicants are required to elect a species for each of the following A-D.

- A. Ultimate species of displaying (i.e. specific linker(s), binding partners, etc.),
- B. Species of library of compounds (e.g. peptides, nucleic acids, specified group of structurally related small organic molecules or inorganic molecules),
- C. Ultimate species of replicable genetic package (e.g. specific viral, phage, or bacterial strain), AND

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D. Ultimate species of assay including desired property and all method steps including, e.g., the method of contacting and what is being contacted.

The species are distinct, each from the other, because they have different structures with different chemical, physical, and/or pharmacological properties or they are different methods requiring different starting materials, method steps, reagents, reaction /assay conditions, and/or produce different results. Therefore, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

4. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend**, telephone number **(703) 308-4548**. The examiner's schedule is normally four, ten-hour days per week that includes Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.  
13 January 2003



**ANDREW WANG**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1800**